IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC., Defendant.	C.A. No. 23-00975-RGA-SRF

PLAINTIFF'S REPLY POST-TRIAL BRIEF REGARDING INFRINGEMENT

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TABLE OF ABBREVIATIONS

'327 patent	U.S. Patent No. 11,826,327
6MWD	6 minute walk distance
Asserted Claims	Claims 1, 5, 6, 9, 14, 17
DPI	Dry powder inhaler
FDA	Food and Drug Administration
FVC	Forced vital capacity
Group 1	WHO Group 1 PH, pulmonary arterial hypertension
Group 3	WHO Group 3 PH, including PH-ILD and PH-COPD
INCREASE	Clinical trial conducted by UTC in patients with PH-ILD. Formally named *Safety and Efficacy of Inhaled Treprostinil in Adult PH With ILD Including CPFE*, ClinicalTrials.gov number NCT02630316
Liq. R. Br.	Liquidia's Responsive Brief on Non-Infringement (D.I. 429)
Liquidia	Liquidia Technologies, Inc.
Liquidia's 505(b)(2) NDA	NDA 213005
NT-proBNP	N-terminal pro-B-type natriuretic peptide
PAH	Pulmonary arterial hypertension (Group 1)
PH	Pulmonary hypertension
PH-ILD	Pulmonary hypertension associated with interstitial lung disease
PFF	Plaintiffs' Proposed Findings of Fact on Infringement and Validity (D.I. 427, D.I. 432) (paragraphs are consecutively numbered)
PI	Prescribing Information (*e.g.*, drug label)
RLD	Reference listed drug
UTC	United Therapeutics Corporation
USPTO	United States Patent and Trademark Office

'327 PATENT – ASSERTED CLAIMS

Claim	Claim Limitation
1[preamble]	A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising
1[a]	administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease
1[b]	an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof
1[c]	in a single administration event that comprises at least 6 micrograms per breath.
5	The method of claim 1, wherein said administering reduces a plasma concentration of NT-proBNP in the patient by at least 200 pg/ml after 8 weeks, 12 weeks, or 16 weeks of the administering.
6	The method of claim 1, wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.
9	The method of claim 1, wherein said administering provides a statistically significant improves of forced vital capacity (FVC) in the patient after 8 weeks, 12, weeks or 16 weeks of the administering.
11 (*not asserted*)	The method of claim 1, wherein said administering is performed by a pulsed inhalation device.
14	The method of claim 11, wherein the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.
17	The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks of the administering.

I. INTRODUCTION

Faced with incontrovertible evidence of infringement, Liquidia takes a bold new tack: questioning the efficacy of its own product. Liquidia's arguments—new and old—lack merit.

The evidence establishes that doctors and patients will practice the Asserted Claims when they administer Yutrepia according to its label. Liquidia has repeatedly represented that Yutrepia will perform equivalently to Tyvaso for patients with PH-ILD. It cannot now call into doubt the efficacy of its own product. Liquidia's other positions are similarly unmoored from the record. Liquidia seeks to "void" its pretrial stipulation to infringing claims 1 and 14 based on an illusory claim construction dispute. Liquidia's new, fabricated measurement method step for claims 5, 6, 9, and 17 is contrary to the claim language, lacks intrinsic evidence, and is waived. Liquidia also repeatedly misstates the law and cites unsupportive authorities. The Court should reject Liquidia's flawed arguments and enter judgment in UTC's favor.

II. LIQUIDIA WARRANTS THAT YUTREPIA AND TYVASO ARE EQUIVALENT

Liquidia presents two contrary narratives regarding Yutrepia's performance. To FDA, insurance payors, doctors, and patients, Liquidia cites data from UTC's INCREASE trial to represent that Yutrepia will achieve equivalent results to Tyvaso. PFF 10-14, 21; PTX-239. To this Court, however, Liquidia argues that Yutrepia is "not 'pharmaceutically equivalent' or 'therapeutically equivalent' to Tyvaso," and as a result, the data from INCREASE cannot be used to establish infringement. Liq. R. Br. at 1-2. These narratives cannot both be true—either Yutrepia will perform as good as or better than Tyvaso did in INCREASE, or it will not. Having no PH-ILD clinical trial of its own, Liquidia's NDA relied exclusively on INCREASE to establish efficacy for PH-ILD. PFF 4-5, 10-11. Liquidia may not now walk back its strategic reliance on INCREASE to avoid the consequence of that decision: infringement.

Liquidia's new position contradicts what it told FDA. Liquidia's regulatory and

commercial strategy for PH-ILD is premised upon Yutrepia performing equivalently to Tyvaso in INCREASE. PFF 10-14. Liquidia told FDA that clinical studies of Yutrepia in PH-ILD were not required because Liquidia would rely on UTC's data from INCREASE (as "described in the Tyvaso PIs and peer-reviewed literature"). PFF 10. Liquidia also performed a bioequivalence study (LTI-102) that created a "definitive PK bridge to the RLD" by showing that Yutrepia and Tyvaso have comparable pharmacokinetics—*i.e.*, patients receive the same amount of treprostinil. PFF 13; PTX-239.000004. Similarly, § 14.2 of the Yutrepia label presents INCREASE as the sole evidence of efficacy in PH-ILD and reports that certain doses of Yutrepia are "equivalent" to doses of Tyvaso used in INCREASE. PFF 9-11. Liquidia's marketing materials also rely on INCREASE to tell doctors, patients, and payors how Yutrepia will perform in PH-ILD. PFF 12; Tr. 109:17-111:8. Finally, Liquidia's CMO, Dr. Rajeev Saggar, offered Rule 30(b)(6) testimony that Yutrepia would be "just as effective as Tyvaso for patients with PH-ILD" and that Yutrepia would "meet or exceed" the performance of Tyvaso in INCREASE.[1] PFF 10-13. This testimony is binding on Liquidia. *See Crawford v. George & Lynch, Inc*., 19 F. Supp. 3d 546, 554 (D. Del. 2013); *Daubert v. NRA Grp., LLC*, 189 F. Supp. 3d 442, 459 (M.D. Pa. 2016), *aff'd*, 861 F.3d 382 (3d Cir. 2017). Liquidia's shameless claim that Yutrepia might not be as effective as advertised should be rejected because it is contrary to Liquidia's prior sworn statements and the trial record.

Yutrepia's 505(b)(2) status does not negate infringement. Liquidia's arguments that Yutrepia is a 505(b)(2) product and "not an AB rated generic" (Liq. R. Br. at 1) are not legally relevant here because neither precludes infringement. Liquidia's 505(b)(2) application, AB-rated or not, relies on UTC's data (just like a generic ANDA applicant would), which shows

[1] Dr. Saggar offered this testimony with full knowledge of ASCENT—Liquidia's ongoing open-label study of Yutrepia in PH-ILD—and did not point to any data suggesting that Yutrepia would perform *worse* than Tyvaso. Tr. 53:25-54:24. Liquidia similarly presented no such data at trial.

infringement. PFF 4-5, 9-11. Liquidia's reliance on *Amarin* is misplaced because, there, the Court expressly declined to give AB rating dispositive force. *Amarin Pharms., Inc. v. Hikma Pharma USA Inc.*, 104 F.4th 1370, 1380 (Fed. Cir. 2024). Neither Liquidia's factual assertions nor its case law put infringement in question. *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 2023 WL 4175334, at *5-*9 (D. Del. June 26, 2023) (finding induced infringement by 505(b)(2) applicant).

Section 6.1 of the Yutrepia label is unavailing. Grasping, Liquidia argues that § 6.1 warns doctors "against extrapolating clinical trial results of one drug to outcomes in clinical practice of a different drug." Liq. R. Br. at 1-2. This too is irrelevant, as that language does not change Liquidia's reliance and representations to FDA regarding the efficacy of Yutrepia for PH-ILD based solely on the INCREASE data. PFF 4-5, 9-11. Notably, Liquidia did not author this statement to limit its instructions; it merely copied the text, word-for-word, from the pre-existing Tyvaso label. *Compare* PTX-291.00007 *with* DTX357.0006. The statement is also limited to "adverse reaction rates" in the context of a clinical trial in PAH patients. PTX-291.00007. No similar "warning" exists in § 14.2, which discusses INCREASE and identifies Yutrepia doses "equivalent" to Tyvaso. *Id.* at 00015-17. Liquidia also misapplies *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, which rejected a patentee's reliance on "fleeting warnings" in the accused label. 99 F. Supp. 3d 461, 490 (D.N.J. 2015). This Court should similarly reject Liquidia's overbroad reading of the warning in § 6.1 of the Yutrepia label.

Equivalence is not limited to dosing. Liquidia's representations that Yutrepia will perform equivalently to Tyvaso in PH-ILD are binding admissions of induced infringement. *See Allergan, Inc. v. Sandoz Inc.*, 2014 WL 12622277, at *10 (E.D. Tex. Jan. 13, 2014), *aff'd*, 796 F.3d 1293 (Fed. Cir. 2015). It is clear from the specification of the '327 patent that Tyvaso achieved the treatment effects required by the Asserted Claims during INCREASE. PFF 4, 6. Therefore if, as

Liquidia's CMO Dr. Saggar testified, Yutrepia will "meet or exceed" the performance of Tyvaso in the context of INCREASE (PFF 9-12), the use of Yutrepia will infringe the Asserted Claims—and Liquidia knows it. *See Allergan,* 2014 WL 12622277, at *10.

Liquidia's attempt to recast its label's use of the term "equivalent" as relating solely "to *dosing*, not performance" (Liq. R. B. at 2) makes no sense. As above, the Yutrepia label uses the term "equivalent" in the specific context of INCREASE, using the comparable pharmacokinetics of Yutrepia and Tyvaso as the basis to assert that Yutrepia is effective. PFF 9-13. That Liquidia's pharmacokinetic data was generated in healthy volunteers does not matter, as Liquidia relies on that data in both its NDA and marketing materials for PH-ILD to show that Yutrepia will be therapeutically equivalent to Tyvaso. *Id.*; PTX-239.00004; *see also Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1131 (Fed. Cir. 2018) (using pharmacokinetics section of label to establish infringement of method claim). Further, *Abbott* and *Belcher* are readily distinguishable because they addressed the doctrine of equivalents in the context of claims directed to compounds and formulations. *Abbott Labs. v. Sandoz Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009); *Belcher Pharms., LLC v. Hospira, Inc.*, 450 F. Supp. 3d 512, 539 (D. Del. 2020), *aff'd*, 11 F.4th 1345 (Fed. Cir. 2021); *cf.* Tr. 165:15-20. The claims here cover *methods of treatment*, and the doctrine of equivalents is not at issue. Liquidia's pharmacokinetic data is plainly relevant because Liquidia relied on it to show equivalent clinical performance to Tyvaso in PH-ILD.

III. LIQUIDIA STIPULATED THAT IT INFRINGES CLAIMS 1 AND 14

On the first day of trial, Liquidia confirmed that it had stipulated to direct and induced infringement of claims 1 and 14. PFF 17. Liquidia maintained this position through the end of trial. Tr. 203:14-21, 945:19-23. This stipulation is binding. *See Allergan, Inc. v. Mankind Pharma Ltd.*, 2024 WL 4213722, at *2-3 (D. Del. 2024) (finding stipulation binding where defendant gave up infringement defense arguments). Now, in post-trial briefing, Liquidia argues for the first time that

its stipulation should be "void" based on an imagined claim construction dispute. Liq. R. Br. at 9. Liquidia's gambit is both improper and devoid of support in the record.

Liquidia mischaracterizes Dr. Nathan's testimony. Liquidia's alleged "change[]" in claim construction (*id.* at 9) is really Liquidia's disagreement with the legal standard for inherent anticipation. Dr. Nathan applied the Court's claim constructions for purposes of both infringement and validity. Tr. 114:3-115:19, 137:5-10, 876:20-877:25, 893:22-894:7. Consistent with these constructions—and contrary to Liquidia's accusations—Dr. Nathan testified that claim 1 *does not* require "virtually all" PH-ILD patients to experience an improvement in exercise capacity:

> **Q.** It's your opinion that Claim 1 requires virtually all of these PH-ILD patients experience an improvement in exercise capacity; correct?
>
> **A.** No. I never said "virtually all."

Tr. 924:23-925:1. Dr. Nathan's subsequent testimony made clear that his use of "virtually all" was a reference only to the legal standard for inherent anticipation, not a claim construction. Tr. 925:2-926:4. Liquidia may disagree with this legal standard—*i.e.*, the same standard applied by the Court during the preliminary injunction phase—but there is no claim construction dispute here, much less a dispute sufficient to "void" Liquidia's binding stipulation. *Cf.* D.I. 96 at 11 (citing *Glaxo Group Ltd. v. Kali Lab'ys, Inc.,* 2005 WL 1398507, at *3 (D.N.J. June 10, 2005)).

Liquidia cannot backtrack on its stipulation. Liquidia had full knowledge of UTC's position when it stipulated that it infringed claims 1 and 14. Indeed, the "virtually all" legal standard for inherent anticipation has long been at issue in this case, and UTC included it in the Pretrial Order. *See* D.I. 96; D.I. 334-4 at 34-36. Nothing material has changed since the parties submitted the Pretrial Order—and UTC's position is identical—so there is no basis for Liquidia to renege. *See Allergan*, 2024 WL 4213722, at *2-3. The trial was conducted based on Liquidia's stipulation, and reopening infringement of claims 1 and 14 would be highly prejudicial to UTC.

IV. LIQUIDIA INFRINGES CLAIMS 5, 6, 9, AND 17

The evidence at trial was clear that (i) the use of Yutrepia according to its label will practice every element of claims 5, 6, 9, and 17; and (ii) Liquidia induces doctors and patients to directly infringe these claims.[2] *See* D.I. 426 at 3-8. Liquidia's arguments to the contrary fail.

A. Claims 5, 6, 9, and 17 do not require a measurement step

Liquidia argues that the use of Yutrepia will not infringe claims 5, 6, 9, or 17 because each of those claims require measuring, collecting, and/or aggregating steps that a clinician would not perform. Liq. R. Br. at 2-4. This argument fails for several independent reasons.

Liquidia waived this new argument. At the pretrial conference, the Court asked if there were any claim construction disputes that required additional briefing. Pretrial Conf. Tr. 29:15-38:5. While arguing a motion *in limine*, Liquidia raised—and the parties ultimately briefed—a dispute regarding the term "PH-ILD." *Id.*; D.I. 373-374; D.I. 378-379. But Liquidia failed to seek construction for its "measurement step" theory. Thus, the Court should reject Liquidia's argument as waived. *Allergan, Inc. v. Barr Labs., Inc.*, 808 F. Supp. 2d 715, 735 (D. Del. 2011); *Exela Pharma Scis., LLC v. Eton Pharms., Inc.*, 620 F. Supp. 3d 108, 140 n.20 (D. Del. 2022).

The claimed methods have no "measurement" step. The POSA would understand claims 5, 6, 9, and 17 to narrow claim 1 to only those methods that achieve the recited treatment effects. D.I. 426 at 8-9; PFF 6, 18-21. The plain language of the claims does not contain any measuring, collecting, or aggregating steps, and the POSA would not read such steps into the claims. *Id.* As Dr. Channick admitted, patients that experience the benefits required by claims 5, 6, 9, and/or 17 will do so whether a measurement is taken or not. *E.g.*, Tr. 208:22-209:7; *see also*

[2] Because Liquidia infringes claim 1, Liquidia sells Yutrepia with the knowledge that its use will meet, *inter alia*, both the limiting preamble (which requires administration with the purpose or expectation of improving exercise capacity) and the PH-ILD limitation of claim 1. *Cf.* D.I. 155, 393.

Tr. 939:16-20. And even if a measurement step were required, doctors measure the outcomes recited in the claims when caring for PH-ILD patients and would do so when administering Yutrepia. Tr. 149:20-150:23, 152:18-153:7, 258:9-259:7, 350:24-351:7, 377:4-14, 491:14-492:4, 767:8-14, 876:23-877:1; DTX10; DTX518; DTX51. Nevertheless, the claims lack a "measuring" step and neither *Limelight* nor *Genentech* require one—they hold only that all *claimed* steps must be "carried out." *Limelight Networks, Inc. v. Akamai Techs., Inc*., 572 U.S. 915, 921 (2014); *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1380 (Fed. Cir. 2022). Liquidia thus conflates the evidence needed to prove infringement with the claimed method itself. Here, the claimed step of "administering" is "carried out" when a doctor or patient administers Yutrepia. D.I. 426 at 8-9. No doctor or patient measurement is required for claims 5, 6, 9, or 17 because Liquidia has already relied on the measured data collected from INCREASE. *Id.*; PFF 6-12, 18-21, 54. In other words, the INCREASE data demonstrates infringement because—according to Liquidia itself—this data shows that the claimed clinical benefits will more likely than not be achieved when Yutrepia is dosed to PH-ILD patients according to the label. D.I. 426 at 8-9; PFF 6-12, 18-21, 54.

Liquidia's label does not preclude infringement. Liquidia argues that infringement is *per se* barred because "Yutrepia is not approved for any dependent claim outcomes, and the label does not even mention them." Liq. R. Br. at 3. This is not the law. Infringement is "based on consideration of all the relevant evidence," not just the product label. *Vanda Pharms.*, 887 F.3d 1117 at 1130. And while data pertaining to a claim limitation in an accused product label may be sufficient to prove infringement, it is not necessary. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060-61 (Fed. Cir. 2010). Indeed, this Court has rejected a similar argument from Liquidia before, holding that the Yutrepia label did not "need to provide hemodynamic data to induce infringement," and instead just needed "to instruct doctors and patients to administer a single event

dose that is therapeutically effective." *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 624 F. Supp. 3d 436, 462-63 (D. Del. 2022). The same principle applies here—the Yutrepia label instructs a method of administration that will achieve the claimed treatment effects. PFF 6-11, 18-21.

Dr. Nathan did not "speculate." Liquidia mischaracterizes Dr. Nathan's testimony. Liq. R. Br. at 3-4. When Dr. Nathan said he would be "entirely speculating," he was responding to a question asking if he knew "*how better or how worse* the results of the INCREASE trial would have been . . . if you had used Yutrepia instead of Tyvaso." Tr. 136:18-23 (emphasis added). This is far from the admission Liquidia attempts to conjure. Dr. Nathan properly relied on Liquidia's own representations that Yutrepia is equivalent to Tyvaso, not speculation. PFF 7-14.

B. Liquidia induces infringement of claims 5, 6, 9, and 17

UTC proved that Liquidia induces doctors and patients to administer inhaled treprostinil in a manner that will directly infringe claims 5, 6, 9, and 17. D.I. 426 at 4-8.

The Yutrepia label is evidence of inducement. Liquidia argues that it cannot induce infringement of claims 5, 6, 9, and 17 because Yutrepia is "not approved" for those benefits. Liq. R. Br. at 4. In essence, Liquidia argues that a Hatch-Waxman defendant can never induce infringement unless the relevant FDA approval recites every outcome in a method claim. This is irreconcilable with Federal Circuit precedent that an accused product's label need not recite every claim limitation to induce infringement. *See, e.g.*, *GlaxoSmithKline v. Teva Pharms. USA*, 7 F.4th 1320, 1330 (Fed. Cir. 2021); *Bone Care Int'l, L.L.C. v. Roxane Labs., Inc.*, 2012 WL 2126896, at *12, *31 (D. Del. June 11, 2012). Here, Liquidia induces infringement because the Yutrepia label instructs a method that Liquidia knows—based on INCREASE—will practice the Asserted Claims. PFF 6-13; *supra* § II. That the Yutrepia label does not reproduce all INCREASE results *verbatim* is irrelevant—Liquidia knew the INCREASE literature and relied on it to obtain FDA approval. PFF 4, 10; *Sanofi v. Watson Labs.*, 875 F.3d 636, 646 (Fed. Cir. 2017); *GlaxoSmithKline*,

7 F.4th at 1330. Liquidia's position on claim 17 is particularly egregious because the Yutrepia label explicitly reports the *exact* 6MWD improvement recited in the claim. PFF 21; *Sanofi-Aventis*, 2023 WL 4175334 at *7 ("even though Defendant's product is indicated for broader purposes than what is claimed in the [asserted patent], Defendant still encourages the patented use").

Evidence beyond the Yutrepia label confirms Liquidia's intent. Liquidia improperly asks the Court to ignore any evidence of induced infringement beyond the Yutrepia label because the label is all that is needed "to safely and effectively prescribe the drug." Liq. R. Br. at 6. Liquidia cites no case that *per se* precludes a patentee from relying on evidence outside the label—and that is because doing so is expressly allowed. *GlaxoSmithKline*, 7 F.4th at 1333, 1335-37. The relevant question here is instead whether Liquidia intentionally encourages doctors and patients to use the drug in a way that will more likely than not infringe the Asserted Claims. *Id*. at 1338. The additional materials UTC presented at trial provide clear evidence of Liquidia's intent. PFF 12-16; D.I. 426 at 3-8. Regardless of their intended audience, these materials plainly demonstrate *Liquidia's* knowledge that Yutrepia will perform equivalently to Tyvaso, and thus will infringe the Asserted Claims. PFF 12; *AstraZeneca*, 633 F.3d at 1056.

Liquidia's "doctor's knowledge" argument is inapposite. Liquidia argues that a physician's knowledge of INCREASE cannot serve as evidence of induced infringement. Liq. R. Br. at 8. Not so. UTC presented evidence that doctors would consult INCREASE literature before prescribing Yutrepia for PH-ILD and would understand the effects that would likely result from the label's "equivalent" dosages. PFF 4, 9-13. Indeed, § 14.2 of the Yutrepia label identifies 6MWD as the "primary endpoint" in INCREASE, which would tell a doctor that there are *other* efficacy benefits beyond exercise capacity. PFF 4, 10-12, 18-21. *See Sanofi-Aventis*, 2023 WL 4175334 at *7 (finding induced infringement based on benefits beyond the listed indication).

Regardless, even if no doctors would consult the literature, *Liquidia* did, thus providing the intent to induce infringement. PFF 9-14, 18-21; *Bone Care*, 2012 WL 2126896, at *31. Finally, Liquidia's cited cases, *Lundbeck* and *Otsuka* (Liq. R. Br. at 8), are inapposite because, as Liquidia admits, both cases relate to label carve outs, which do not exist here.

Liquidia fails to distinguish UTC's cases. Liquidia claims that, unlike the defendants in cases UTC cited in its Opening Brief, "Liquidia made no express or implied representation that Yutrepia has equivalent efficacy to Tyvaso." Liq. R. Br. at 7. That is simply wrong. Liquidia made those representations in its NDA, Yutrepia label, marketing materials, and sworn Rule 30(b)(6) testimony. *Supra* § II; PFF 9-14. Liquidia's attempt to distinguish this Court's finding on induced infringement of the '793 patent falls flat for the same reasons discussed above. *Supra* § IV.A. Liquidia similarly fails to distinguish *Sanofi-Aventis*, where this Court found infringement of claims directed to "increasing survival" because the label discussed a clinical trial that used survival as an endpoint. 2023 WL 4175334 at *6-9.[3] Likewise, the Yutrepia label discloses INCREASE, which had endpoints directed to each of the benefits required by claims 5, 6, 9, and 17. PFF 6, 10-12, 18-21. While not all of these endpoints appear in the label, they were all disclosed in the peer-reviewed literature relating to INCREASE, which Liquidia has repeatedly cited as evidence of Yutrepia's effects. PFF 10-14, 18-20; PTX-239. That is more than enough.

V. CONCLUSION

UTC has proven that Liquidia infringes each Asserted Claim. UTC respectfully requests that the Court enter judgment in its favor and grant relief under 35 U.S.C. §§ 271(e)(2) and 271(e)(4), along with any further relief the Court deems just and proper.

[3] Also like here, in *Sanofi-Aventis*, the method of treatment claims were non-obvious despite the presence of promising pilot studies and "anecdotal" accounts of efficacy in the prior art. 2023 WL 4175334 at *10-15. The Court found that the POSA's mere "hope" or "cautious optimism" in an "unpredictable" field did not support a reasonable expectation of success. *Id.* at 14 & n.8.

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July 31, 2025

CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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